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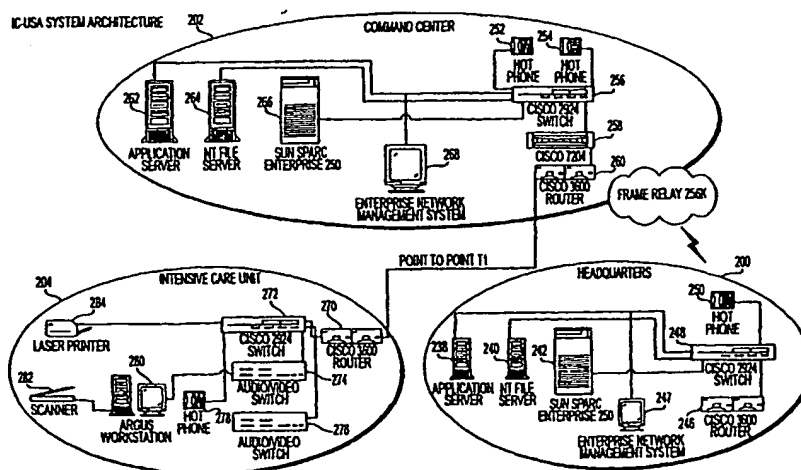
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(54) Title: SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)



(57) Abstract: A system and method for providing continuous expert network critical care services from a remote location. A plurality of intensive care units (ICU's) with associated patient monitoring instrumentation is connected over a network to a command center which is manned by intensivists 24 hours a day, 7 days a week. The intensivists are prompted to provide critical care by a standardized series of guideline algorithms for treating a variety of critical care conditions. Intensivists monitor the progress of individual patients at remote intensive care units. A smart alarm system provides alarms to the intensivists to alert the intensivists to potential patient problems so that intervention can occur in a timely fashion. A data storage/data warehouse function analyzes individual patient information from a plurality of command centers and provides updated algorithms and critical care support to the

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Title: System and Method for Providing Continuous, Expert Network  
Critical Care Services from a Remote Location(s)**

**BACKGROUND OF THE INVENTION**

**1. Field of the Invention**

This invention relates generally to the care of patients in Intensive Care Units (ICUs). More particularly this invention is a system and method for care of the critically ill that combines a real-time, multi-node telemedicine network and an integrated, computerized patient care management system to enable specially-trained Intensivists to provide 24-hour/7-day-per-week patient monitoring and management to multiple, geographically dispersed ICUs from both on-site and remote locations.

**2. Background Art**

While the severity of illness of ICU patients over the past 15 years has increased dramatically, the level of and type of physician coverage in most ICUs has remained constant. Most ICU patients receive brief minutes of attention during morning rounds from physicians with limited critical care experience. During the remainder of the day and night, nurses are the primary caregivers, with specialists called only after patient conditions have started to deteriorate. The result of this mismatch between severity of illness and physician coverage is an unacceptably high ICU mortality rate (10% nationwide), and a high prevalence of avoidable errors that result in clinical complications.

In 1998, an Institute of Medicine Roundtable determined that avoidable patient complications were the single largest problem in medical care delivery. In another prominent 1998 study of 1000 patients, 46% experienced an avoidable adverse event in care, with 40% of these errors resulting in serious disability or death.

The physicians who can remedy this situation are in critically short supply. Numerous studies have shown that Intensivists (physicians who have trained and board certified in Critical Care Medicine) can markedly improve patient outcomes. However, only one-third of all ICU patients ever has an Intensivist involved in their care, and the number of Intensivists would need to increase tenfold (nationally) to provide 24-hour

1 coverage to all ICU patients. With the rapid aging of the population, this shortfall of  
2 expertise is going to increase dramatically.

3 Even where Intensivists are present (and especially where they are not), patients  
4 suffer from unnecessary variation in practice. There is little incentive for physicians to  
5 develop and conform to evidence-based best practices (it takes significant work and a  
6 change in behavior to develop and implement them). This variation contributes to sub-  
7 optimal outcomes, in both the quality and cost of care delivered to ICU patients.

8 What is needed is a redesigning of the critical care regimen offered to patients in  
9 an ICU. Rather than the consultative model where a periodic visit takes place and the  
10 doctor then goes away, a more active 24-hour intensivist managed care is required.  
11 Further, technology that leverages the intensivists' expertise and standardizes the care  
12 afforded to patients in an ICU is required. Further, continuous feedback to improve the  
13 practice of intensivists in an ICU is necessary to provide the intervention required to  
14 minimize adverse events. This invention seeks to provide new methods for managing and  
15 delivering care to the critically ill.

16 Attempts to automate various aspects of patient care have been the subject of  
17 various inventions. For example, U.S. Patent No. 5,868,669 to Iliff was issued for  
18 "Computerized Medical Diagnostic and Treatment Advice System." The disclosed  
19 invention is for a system and method for providing computerized knowledge based  
20 medical diagnostic and treatment advice to the general public over a telephone network.

21 U.S. Patent No. 5,823,948 to Ross, Jr. et al was issued for "Medical Records  
22 Documentation, Tracking and Order Entry System". The disclosed invention is for a  
23 system and method that computerizes medical records, documentation, tracking and order  
24 entries. A teleconferencing system is employed to allow patient and medical personnel to  
25 communicate with each other. A video system can be employed to videotape a patient's  
26 consent.

27 U.S. Patent No. 4,878,175 to Norden-Paul et al. was issued for "Method for  
28 Generating Patient-Specific Flowsheets By Adding/Deleting Parameters." The disclosed  
29 invention is for an automated clinical records system for automated entry of bedside  
30 equipment results, such as an EKG monitor, respirator, etc. The system allows for  
31 information to be entered at the bedside using a terminal having input means and a video  
32 display.

1           U.S. Patent No. 5,544,649 to David et al. was issued for "Ambulatory Patient  
2   Health Monitoring Techniques Utilizing Interactive Visual Communications." The  
3   disclosed invention is for an interactive visual system, which allows monitoring of patients  
4   at remote sites, such as the patient's home. Electronic equipment and sensors are used at  
5   the remote site to obtain data from the patient, which is sent to the monitoring site. The  
6   monitoring site can display and save the video, audio and patient's data.

7           U.S. Patent No. 5,867,821 to Ballantyne et al. was issued for "Method and  
8   Apparatus for Electronically Accessing and Distributing Personal Health Care Information  
9   and Services in Hospitals and Homes." The disclosed invention is for an automated  
10   system and method for distribution and administration of medical services, entertainment  
11   services, and electronic health records for health care facilities.

12          U.S. Patent No. 5,832,450 to Myers et al. issued for "Electronic Medical Record  
13   Using Text Database." The disclosed invention is for an electronic medical record system,  
14   which stores data about patient encounters arising from a content generator in freeform  
15   text.

16          U.S. Patent No. 5,812,983 to Kumagai was issued for "Computer Medical File and  
17   Chart System." The disclosed invention is for a system and method which integrates and  
18   displays medical data in which a computer program links a flow sheet of a medical record  
19   to medical charts.

20          U.S. Patent No. 4,489,387 to Lamb et al. was issued for "Method and Apparatus  
21   for Coordinating Medical Procedures." The disclosed invention is for a method and  
22   apparatus that coordinates two or more medical teams to evaluate and treat a patient at the  
23   same time without repeating the same steps.

24          U.S. Patent No. 4,731,725 to Suto et al. issued for "Data Processing System  
25   which Suggests a Pattern of Medical Tests to Reduce the Number of Tests Necessary to  
26   Confirm or Deny a Diagnosis." The disclosed invention is for a data processing system  
27   that uses decision trees for diagnosing a patient's symptoms to confirm or deny the  
28   patient's ailment.

29          U.S. Patent No. 5,255,187 to Sorensen issued for "Computer Aided Medical  
30   Diagnostic Method and Apparatus." The disclosed invention is for an interactive  
31   computerized diagnostic system which relies on color codes which signify the presence or

1 absence of the possibility of a disease based on the symptoms a physician provides the  
2 system.

3 U.S. Patent No. 5,839,438 to Chen et al. issued for "Intelligent Remote Visual  
4 Monitoring System for Home Health Care Service." The disclosed invention is for a  
5 computer-based remote visual monitoring system, which provides in-home patient health  
6 care from a remote location via ordinary telephone lines.

7 U.S. Patent No. 5,842,978 to Levy was issued for "Supplemental Audio Visual  
8 Emergency Reviewing Apparatus and Method." The disclosed invention is for a system  
9 which videotapes a patient and superimposes the patient's vital statistics onto the  
10 videotape.

11 While these invention provide useful records management and diagnostic tool,  
12 none of them provides a comprehensive method for monitoring and providing real time  
13 critical care at disparate ICU's. In short, they are NOT designed for critical care. Further,  
14 none of these inventions provide for the care of a full time intensivist backed by  
15 appropriate database and decision support assistance in the intensive care environment.  
16 What would be useful is a system and method for providing care for the critically ill that  
17 maximizes the presence of an intensivist trained in the care of the critically. Further such  
18 a system would standardize the care in ICU's at a high level and reduce the mortality rate  
19 of patients being cared for in ICU's

#### 20 SUMMARY OF THE INVENTION

21 The present invention provides a core business of Continuous Expert Care  
22 Network (CXCN) solution for hospital intensive care units (ICUs). This e-solution uses  
23 network, database, and decision support technologies to provide 24-hour connectivity  
24 between Intensivists and ICUs. The improved access to clinical information and  
25 continuous expert oversight leads to reduced clinical complications, fewer medical errors,  
26 reduced mortality, reduced length of stay, and reduced overall cost per case.

27 The technology of the present invention as explained below can be implemented  
28 all at once or in stages. Thus the technology, as more fully explained below is available in  
29 separate components to allow for the fact that hospitals may not be able to implement all  
30 of the technology at once. Thus modular pieces (e.g. videoconferencing, vital sign  
31 monitoring with smart alarms, hand-held physician productivity tools, etc.) can be  
32 implemented, all of which can add value in a stand-alone capacity. First amongst these

1 offerings will be an Intensivist Decision Support System, a stand-alone software  
2 application that codifies evidence-based, best practice medicine for 150 common ICU  
3 clinical scenarios. These support algorithms are explained more fully below.

4 The "Command Center" model, again as more fully set forth below, will ultimately  
5 give way to a more distributed remote management model where Intensivists and other  
6 physicians can access ICU patients and clinicians (voice, video, data) from their office or  
7 home. In this scenario, the present invention will be available in hospital applications that  
8 centralize ICU information, and offer physicians web-based applications that provide them  
9 with real-time connectivity to this information and to the ICUs. This access and  
10 connectivity will enable physicians to monitor and care for their patients remotely. These  
11 products will be natural extensions and adaptations of the present invention and the  
12 existing applications disclosed herein that those skilled in the art will appreciate and which  
13 do not depart from the scope of the invention as disclosed herein.

14 The present invention addresses these issues and shortcomings of the existing  
15 situation in intensive care, and its shortfalls via two major thrusts. First, an integrated  
16 video/voice/data network application enables continuous real-time management of ICU  
17 patients from a remote setting. Second, a client-server database application B integrated to  
18 the remote care network B provides the data analysis, data presentation, productivity tools  
19 and expert knowledge base that enables a single Intensivist to manage the care of up to 40  
20 patients simultaneously. The combination of these two thrusts B care management from a  
21 remote location and new, technology-enhanced efficiency of Intensivist efforts B allows  
22 health care systems to economically raise the standard of care in their ICUs to one of 24x7  
23 continuous Intensivist oversight.

24 It is therefore an object of the present invention to reduce avoidable complications  
25 in an ICU.

26 It is a further object of the present invention to reduce unexplained variations in  
27 resource utilization in an ICU.

28 It is a further objective of the present invention to mitigate the serious shortage of  
29 intensivists.

30 It is yet another objective of the present invention to reduce the occurrence of  
31 adverse events in an ICU.

1           It is a further objective of the present invention to standardize the care at a high  
2 level among ICUs.

3           It is yet another objective of the present invention to reduce the cost of ICU care.

4           It is yet another objective of the present invention to dramatically decrease the  
5 mortality in an ICU.

6           It is yet another objective of the present invention to bring information from the  
7 ICU to the intensivist, rather than bring the intensivist to the ICU.

8           It is a further objective of the present invention to combine tele-medical systems  
9 comprising two-way audio/video communication with a continuous real time feed of  
10 clinical information to enable the intensivist to oversee care within the ICU.

11           It is a further objective of the present invention to allow intensivists to monitor  
12 ICUs from a site remote from each individual ICU.

13           It is a further objective of the present invention to bring organized detailed clinical  
14 information to the intensivist, thereby providing standardized care in the ICU.

15           It is yet another objective of the present invention to utilize knowledge-based  
16 software to use rules, logic, and expertise to provide preliminary analysis and warnings for  
17 the intensivists.

18           It is a still further objective of the present invention to provide a video visitation  
19 system that allows persons at remote locations using remote terminals to participate in a  
20 video/audio conferencing session with a patient or his/her caregivers local to a patient site.

21           The present invention comprises a command center/remote location, which is  
22 electronically linked to ICUs remote from the command center/remote location. The  
23 command center/remote location is manned by intensivists 24 hours a day, seven days per  
24 week. Each ICU comprises a nurse's station, to which data flows from individual beds in  
25 the ICU. Each patient in the ICU is monitored by a video camera, as well as by clinical  
26 monitors typical for the intensive care unit. These monitors provide constant real time  
27 patient information to the nurse's station, which in turn provides that information over a  
28 dedicated T-1 (high bandwidth) line to the ICU command center/remote location. As  
29 noted earlier, the command center/remote location is remote from the ICU, thereby  
30 allowing the command center/remote location to simultaneously monitor a number of  
31 patients in different ICUs remote from the command center/remote location.



1           At each command center/remote location, video monitors exist so that the  
2           intensivist can visually monitor patients within the ICU. Further, the intensivist can steer  
3           and zoom the video camera near each patient so that specific views of the patient may be  
4           obtained, both up close and generally. Audio links allow intensivists to talk to patients and  
5           staff at an ICU bed location and allow those individuals to converse with the intensivist.

6           Clinical data is constantly monitored and presented to the command center/remote  
7           location in real time so that the intensivist can not only monitor the video of the patient but  
8           also see the vital signs as transmitted from the bedside. The signals from the clinical data  
9           and video data are submitted to a relational database, which comprises 1) standardized  
10          guidelines for the care of the critically ill, 2) various algorithms to support the intensive  
11          care regimen, 3) order writing software so that knowledge-based recommendations and  
12          prescriptions for medication can be made based upon the clinical data, and 4) knowledge-  
13          based vital sign/hemodynamic algorithms that key the intensivist to engage in early  
14          intervention to minimize adverse events.

15          The advantage of the present invention is that intensivists see all patients at a  
16          plurality of ICU's at all times. Further, there is a continuous proactive intensivist care of  
17          all patients within the ICU, thereby minimizing adverse events. Intervention is triggered  
18          by evidence-based data-driven feedback to the intensivist so that standardized care can be  
19          provided across a plurality of ICUs.

20          The economic benefits of the present invention are manifold. For the first time,  
21          24-hour a day, seven day a week intensivist care for patients in an ICU can be obtained.  
22          Further, more timely interventions in the care of the patients can be created by the  
23          knowledge-based guidelines of the present invention, thereby minimizing complications  
24          and adverse events. This in turn will lead to a reduced mortality within the ICU, and  
25          hence, a reduced liability cost due to the dramatic reduction in avoidable errors in health  
26          care.

27          By providing timely interventions, the length of stay within the ICU can be greatly  
28          reduced, thereby allowing more critically ill patients to be cared for in the ICU.

29          In addition, by reviewing and standardizing the care afforded to patients in an ICU,  
30          a more standardized practice across a variety of ICUs can be achieved. This will lead to  
31          more cost-effective care within the ICU, and reduced ancillary cost for the care of the  
32          critically ill.

1           The overall architecture of the present invention comprises a "pod." The pod  
2 comprises a tele-medicine command center/remote location connected to a plurality  
3 multiple ICUs at various locations. The connection between the command center/remote  
4 location and the ICUs is via a dedicated wide-area network linking the ICUs to the  
5 command center/remote location and a team of intensivists who integrate their services to  
6 provide 24-hour, seven day a week care to all of the pod ICUs.

7           The pod is connected via a wide-area network using dedicated T-1 lines, for  
8 example, with redundant backup. This network provides reliable, high speed secure  
9 transmission of clinical data and video/audio signals between each patient room and the  
10 command center/remote location. The use of a T-1 line is not meant as a limitation. It is  
11 expected that more and higher bandwidth networks will become available. Such high  
12 bandwidth networks would come within the scope of the invention as well.

13           Each patient room is equipped with a pan/tilt/zoom video camera with audio and  
14 speaker to enable full videoconferencing capability. In addition, computer workstations  
15 are dedicated for exclusive physician use in each ICU, preferably at the nurse's station.  
16 Intensivists use the workstations to view patient information, consult decision support  
17 information, record their notes, and generate patient orders.

18           The patient management software used by intensivists is provided across the pod.  
19 Updates and changes made to the record are available at both the ICU and the command  
20 center/remote location for any given patient.

21           Each command center/remote location contains at least three workstations: one for  
22 the intensivist, one for the critical care registered nurse, and one for a clerk/administrative  
23 person.

24           The intensivist workstation comprises separate monitors for displaying ICU video  
25 images of patients and/or ICU personnel, output from bedside monitoring equipment,  
26 patient clinical data comprising history, notes, lab reports, etc., and decision support  
27 information. The staff at the command center/remote location are able to activate and  
28 control the cameras in each patient's room so that appropriate visual views of the patient  
29 can be generated.

30           Intensivists are able to switch between rooms and patients and can monitor at least  
31 two rooms simultaneously via the video screens. Patient data such as X-ray and ECG

1 images are scanned and transmitted to the command center/remote location upon request  
2 of the intensivist.

3 Remote patient management is utilized in the present invention's critical care  
4 program to supplement traditional onsite care. The rationale underlying the remote patient  
5 management of the present invention is that critically ill patients are inherently unstable  
6 and require continuous expert care that is not now offered in existing ICU monitoring  
7 regimens. Further, remote monitoring allows a single intensivist to care for patients in  
8 multiple ICU locations, thereby creating an efficiency that makes continuous care feasible.

9 Remote intensivist care of the present invention is proactive. Intensivists will  
10 order needed therapies and check results of tests and monitor modalities in a more timely  
11 fashion than is currently offered. Patients can be observed visually when needed using the  
12 ceiling-mounted cameras in each room.

13 Command center/remote location personnel communicate with ICU staff through  
14 videoconferencing and through "hot phones," which are dedicated telephones directly  
15 linked between the command center/remote location and the ICU. These communications  
16 links are used to discuss patient care issues and to communicate when a new order has  
17 been generated.

18 Intensivists document important events occurring during their shift in progress  
19 notes generated on the command center/remote location computer terminal.

20 Intensivists detect impending problems by intermittently screening patient data,  
21 including both real time and continuously stored vital sign data. Patient severity of illness  
22 determines the frequency with which each patient's data is reviewed by the intensivists.

23 A video visitation system allows Remote Visitation Participants (RVPs) at remote  
24 terminals to participate in a video/audio conferencing session with a Local Visitation  
25 Participant(s) (LVPs) (e.g., the patient or the patient's caregivers) at a patient site.

#### 26 BRIEF DESCRIPTION OF THE DRAWINGS

27 Figure 1 illustrates the logical data structure for billing, insurance and demographic  
28 information

29 Figure 1A illustrates the logical data structure for billing, insurance and  
30 demographic information (cont)

31 Figure 2 illustrates the command center logical data structure

32 Figure 2A illustrates the command center logical data structure (cont)

1           Figures 3 illustrates the logical data structure for creating a medical history

2           Figure 4 illustrates the logical data structure for creating notes relating to patient  
3 treatment and diagnosis

4           Figure 4A illustrates the logical data structure for creating notes relating to patient  
5 treatment and diagnosis (cont)

6           Figure 4B illustrates the logical data structure for creating notes relating to patient  
7 treatment and diagnosis (cont)

8           Figure 5 illustrates the logical data structure for entry of medical orders

9           Figure 6 illustrates the logical data structure for patient care, laboratory testing and  
10 diagnostic imaging

11          Figure 6A illustrates the logical data structure for patient care, laboratory testing  
12 and diagnostic imaging (cont)

13          Figure 7 illustrates the logical data structure for categories of information that are  
14 permitted to be presented to intensivists and other care givers by the system

15          Figure 8 illustrates the logical data structure for documenting patient vital signs

16          Figure 8A illustrates the logical data structure for documenting patient vital signs  
17 (cont)

18          Figure 9 illustrates the distributed architecture of the present invention

19          Figure 10 illustrates the system architecture of the present invention

20          Figure 11 illustrates the decision support algorithm for decision support algorithm  
21 for diagnosis and treatment of pancreatitis.

22          Figure 12 illustrates the vital signs data flow.

23          Figure 13A illustrates capture and display of diagnostic imaging.

24          Figure 13B illustrates establishing videoconferencing in the present invention.

25          Figure 14 illustrates the physician resources order writing data interface of the  
26 present invention.

27          Figure 15 illustrates the physician resources database data interface of the present  
28 invention.

29          Figure 16 illustrates the automated coding and billing system integrated with the  
30 workflow and dataflow of the present invention.

31          Figure 17 illustrates the order writing data flow of the present invention.

32          Figure 18 illustrates the event log flow of the present invention.

- 1           Figure 19 illustrates the smart alarms implementation of the present invention.
- 2           Figure 20 illustrates the procedure note creation and line log for the present
- 3 invention.
- 4           Figure 21 illustrates the acalculous cholecystitis decision support algorithm
- 5           Figure 22 illustrates the adrenal insufficiency decision support algorithm
- 6           Figure 23 illustrates the blunt cardiac injury decision support algorithm
- 7           Figure 24 illustrates the candiduria decision support algorithm
- 8           Figure 25 illustrates the cervical spine injury decision support algorithm
- 9           Figure 26 illustrates the oliguria decision support algorithm
- 10          Figure 26A illustrates the oliguria decision support algorithm (cont)
- 11          Figure 26B illustrates the oliguria decision support algorithm (cont)
- 12          Figure 27 illustrates the open fractures decision support algorithm
- 13          Figure 28 illustrates the pancreatitis decision support algorithm
- 14          Figure 29 illustrates the penicillin allergy decision support algorithm
- 15          Figure 30 illustrates the post-op hypertension decision support algorithm
- 16          Figure 31 illustrates the pulmonary embolism decision support algorithm
- 17          Figure 31A illustrates the pulmonary embolism decision support algorithm (cont)
- 18          Figure 32 illustrates the seizure decision support algorithm
- 19          Figure 33 illustrates the SVT determination decision support algorithm
- 20          Figure 33A illustrates the SVT unstable decision support algorithm
- 21          Figure 34 illustrates the wide complex QRS Tachycardia decision support
- 22 algorithm
- 23          Figure 34A illustrates the wide complex QRS Tachycardia decision support
- 24 algorithm (cont)
- 25          Figure 35 illustrates the assessment of sedation decision support algorithm
- 26          Figure 35A illustrates the assessment of sedation decision support algorithm (cont)
- 27          Figure 36 illustrates the bolus sliding scale midazolam decision support algorithm
- 28          Figure 37 illustrates the sedation assessment algorithm decision support algorithm
- 29          Figure 38 illustrates the short term sedation process decision support algorithm
- 30          Figure 39 illustrates the respiratory isolation decision support algorithm
- 31          Figure 40 illustrates the empiric meningitis treatment decision support algorithm
- 32          Figure 41 illustrates the ventilator weaning decision support algorithm

1 Figure 41A illustrates the ventilator weaning decision support algorithm (cont)

2      Figure 42 illustrates the warfarin dosing decision support algorithm

3      Figure 43 illustrates the HIT-2 diagnostic decision support algorithm

Figure 44 illustrates a video visitation system according to an alternate embodiment of the present invention

## 6 Definitions of Terms and Data

7       **Definitions of Modules**       In the following Detailed description of the Invention, a  
8       number of modules and procedures are described. For purposes of definitions, the  
9       following module definitions apply and are more fully amplified in the descriptions of the  
10      figures that follow:

11 Term Definitions:

12 Following are a series of definitions for certain terms used in this specification:

13 Insurance carrier: This is a table of all the valid insurance carriers listed in the  
14 system of the present invention.

15 Patient guarantor: Provides the insurance guarantor information for a given patient.

16 **Patient information:** Provides demographic information for each patient.

Medical event date history: This contains the various disorders of the patient and the dates associated with major medical events relating to those disorders.

19 **Medical history:** Contains non-major system medical history of a patient.

20 Drug: Contains what medication and allergies have been identified for a patient at  
21 admission.

22      **Address:** Contains the address or addresses for a given patient.

23 Patient visit: There may be multiple records for any given patient, since the patient  
24 may visit the ICU on more than one occasion. This file contains a record of each visit to  
25 an ICU by a patient.

26 Physician-patient task: Contains the task that had been defined for each patient.

27 Present illness: This contains a textural description of the patient illness for the  
28 specific ICU visit.

Physical exam: This contains the information gathered as a result of a physical examination of the patient during the admission to the ICU.

31 Surgical fluids: This provides all the information related to the fluids provided  
32 during surgery.

1           Surgery: This contains all information pertaining to any surgical procedure  
2 performed on a patient while the patient is at the ICU.

3           Patient admit: This provides general information that needs to be gathered when a  
4 patient is admitted into the ICU.

5           Medical orders: This provides the general information for all types of medical  
6 orders associated with a given patient.

7           Daily treatment: This contains the treatment provided for a given patient on a given  
8 day.

9           Daily diagnosis: This contains the daily diagnosis for a given patient, which  
10 includes neurological, cardiological, pulmonary, renal, endocrinological, and any other  
11 diagnosis that may be associated with a patient.

12           Vital sign information is also critical to the administration of care in the ICU. A  
13 number of different modules collect information relating to patient vital signs. For  
14 example:

15           Patient admit: This provides the general information that needs to be gathered  
16 when a patient is admitted to the ICU.

17           Patient visit: This contains a record of each visit to an ICU by a patient.

18           Patient: Provides demographic information for each patient.

19           Vital sign header: This contains general information related to the vital sign data  
20 for the particular patient.

21           Vital sign: Contains the vital sign data taken at specific intervals for a given  
22 patient.

23           Hospital: This contains identifying information for a particular hospital where the  
24 care is given.

25           ICU bed: Contains the association for identifying which beds are in a given ICU.

26           Command center/remote location definitions and modules have also been created  
27 for the present invention to allow for the orderly storage and retrieval and entering of data.

28           For example:

29           Physician-physician (such as nurses and LPN and the like): Contains the names of  
30 all of the physicians and physician extenders for the command center/remote location as  
31 well as for ICUs associated with the command center/remote location.

1           Communication: Contains all of the various types of communication vehicles used  
2 to contact an individual physician or physician extender.

3           Physician role: Contains the role a physician is playing for a given patient, (i.e.,  
4 primary care, consultant, etc.)

5           Patient: Provides demographic information for each patient.

6           Command center/remote location: Provides identifying information for a particular  
7 command center/remote location.

8           Hospital: Contains identifying information for a particular hospital wherein an ICU  
9 is located.

10          ICU: Contains identifying information for an ICU at a hospital.

11          ICU bed: Contains the association for identifying which beds are in a given  
12 hospital.

13          ICU patient location: Provides the association between an ICU and a patient and  
14 identifies where a patient is located within an ICU in a particular hospital.

15          The order entry functionality of the present invention provides a critical service for  
16 obtaining information on the patient during admission, medical orders, and procedures  
17 provided to the patient during the ICU stay. For example:

18          Radiology: Contains all radiology performed on a particular patient.

19          Radiology results: Contains the results of each radiology test performed on the  
20 particular patient.

21          Drugs: Contains all relevant information for all the drugs that a patient has been  
22 administered.

23          Laboratory: Contains all laboratory tests ordered for a patient.

24          Microbiology result: Contains the results of microbiology organisms taken on a  
25 patient.

26          Laboratory result: Contains the results for a laboratory test ordered for a particular  
27 patient.

## 28                           **DETAILED DESCRIPTION OF THE INVENTION**

29          The present invention is a system and method for remote monitoring of ICU's from  
30 a distant command center/remote location. By monitoring a plurality of ICU's remotely,  
31 intensivists can better spread their expertise over more ICU beds that heretofore



1       achievable. The presence of 24-hour a day/7 day-per-week intensivist care dramatically  
2       decreases the mortality rates associated with ICU care.

3               Referring to Figures 1 and 1A, the Billing and Demographic data structure of the  
4       present invention is illustrated. Patient demographic information **9010** is collected on the  
5       particular patient. This information comprises all the typical kinds of information one  
6       would normally gather on a patient such as first name, last name, telephone number,  
7       marital status, and other types of information. Patient insurance information **9012** is  
8       collected and associated with the patient demographic information **9010**. Patient  
9       insurance information **9012** relates to information on the type of accident and related  
10      information such as employment, employer name, place of service, and other information  
11      that would relate to the accident that actually occurred (if at all) and which would have to  
12      be reported to an insurance agency. This information is associated with the patient  
13      demographic information which assigns the unique patient ID to the particular patient.

14             Insurance plan information **9008** is also created and stored and comprises  
15      insurance carrier ID's, the plan name, policy number, and group number. This  
16      information on the insurance plan **9008** is also associated with the patient ID and  
17      demographic information **9010**.

18             Physician information **9002** is also created and stored for each physician associated  
19      with the system of the present invention. Information such as first and last name,  
20      credentials, and other information concerning the physician is saved. In addition, the  
21      physician's role is identified **9004** and information concerning the physician and the  
22      physician's role is associated with the particular patient via the patient ID stored in the  
23      demographic information **9010**.

24             Patient's are entered into the hospital by a hospital representative **9006** who has a  
25      representative ID which also is ultimately associated with the patient ID. In addition,  
26      communications data **9000** is stored concerning how a representative can be reached (cell  
27      phone, home phone etc.).

28             Referring now to Figure 1A, the Overall Billing and Insurance data structure is  
29      illustrated. An insurance provider number **9014** is also stored in the system. Each  
30      physician is given a provider number and provider ID by each insurance company. Thus  
31      data must be stored regarding the ID that is given to a particular physician by each  
32      insurance provider. This information is also stored and can be associated ultimately with

1 treatment of the patient.

2 Each patient admitted to the hospital and to the ICU has a patient visit ID  
3 associated with the patient 9017. This visit ID has patient ID information, ICU  
4 information, admission date, and other information relevant to the specific visit. This  
5 information is illustrated in Figure 1A. The visit ID 9017 is associated with the patient ID  
6 9010 so that each visit can be tracked by patient.

7 Insurance carrier information 9018 is stored by the system and is associated with  
8 the insurance plan information 9008 as appropriate. Thus the particular insurance carrier  
9 with its name, address, and other identifying information 9018 is associated with the type  
10 of plan 9008 carried by the patient. The insurance carrier information 9018 together with  
11 the insurance plan information 9008 is associated with the patient via the patient ID  
12 information 9010.

13 Patient address information 9020 and 9022 are collected for each individual patient  
14 and associated with the patient demographic information 9010. If there is a patient  
15 guarantor, this information is obtained and stored with information on the guarantor 9026.  
16 Such information as the guarantor's first and last name, date of birth, and other  
17 information is stored and is illustrated in Figure 1A. Further, the guarantor's address 9024  
18 is also collected and ultimately associated with the patient demographic information 9010.

19 Referring to Figures 2 and 2A, the Command Center logical data structure is  
20 illustrated.

21 The various information associated with demographic and insurance information is again  
22 used to manage the care and operations of the command center. Therefore,  
23 communications information 9000 is combined with physician and physician extender (i.e.  
24 nurse, LPN and the like) information 9002 and physician role 9004 to be associated with  
25 the demographic information 9010. The patient visit information 9017 together with this  
26 information is associated with the patient's location which has a unique identifier 9030.  
27 Each location ID has patient ID information and visit ID information associated with it.

28 Referring now to Figure 2A, the Command Center logical data structure  
29 illustration continues. Each ICU bed has an associated location ID which comprises  
30 hospital ICU information, room number, and bed number 9038. In addition, and as  
31 described earlier, instrumentation such as cameras are also associated with the particular  
32 patient. Therefore the camera setting 9040 will have a location ID relating to the ICU bed

1 as well as have camera value settings and associated camera identifier information.

2 Each ICU bed 9038 is associated with an ICU 9032. Each ICU has information  
3 associated with it that uniquely identifies the ICU as being associated with the particular  
4 hospital, and having particular phone numbers, fax numbers, work space addresses, and  
5 other information, that help to identify the ICU.

6 As noted above, each ICU is associated with a hospital 9034. Each hospital has a  
7 unique identifier, as well as its own name, address, and other identifying information.  
8 Further, since each hospital ICU is to be coordinated through a remote command center,  
9 information on the remote command center 9036 is associated with the hospital  
10 information. Each command center has a unique ID and has associated address  
11 information stored as well.

12 Thus in the Command Center logical data structure, patient ID information 9010 is  
13 linked to a patient location 9030 which in turn is associated with an ICU bed 9038 each of  
14 which beds are uniquely associated an ICU 9032 which is associated with a hospital 9034  
15 which in turn has the ICU managed by a command center 9036.

16 An integral part of the system of the present invention is the recording of medical  
17 history. Referring to Figure 3, the logical relationship among data elements for medial  
18 history is illustrated. Patient visit information 9017 combined with the physician-  
19 physician extender information 9002 is combined with specific note-taking information  
20 9042. The note information comprises the date and time the notes are taken as well as the  
21 note type. The note ID is fed information from the medical history item 9044, which has  
22 its own unique medical ID associated with it. This information comprises medical text,  
23 category of information, and other information relevant to the medical history. As noted,  
24 this information for medical history 9044 is associated with a note ID 9042, which in turn  
25 is associated with the patient visit and physician information 9017 and 9002.

26 Referring to Figure 4, 4A, and 4B, the note-keeping logical data structure of the  
27 present invention is illustrated. As noted earlier, the note ID 9042 combines information  
28 from visit ID, treating physician, and other information relating to the time the note was  
29 entered. Other information is associated with the note ID. Referring first to Figure 4, the  
30 patient visit information 9017, is associated with the note ID 9042. Various procedural  
31 information 9046 is kept by the system of the present invention and is associated with the  
32 visit ID 9017. Physicians are able to create free text patient illness notations 9048 and

1 associate them with the note 9042. Similarly, free text information regarding functioning  
2 of the system 9050 is permitted and also associated with notes regarding the particular  
3 patient and procedure 9042.

4 Specific notes regarding, for example, surgical procedures are also kept. Surgery  
5 notes 9054 are associated with a particular note ID and have such information as  
6 anesthesia, surgical diagnosis, elective information, and other related surgical information.

7 Surgical fluids 9052 administered during the course of surgery are associated with the  
8 surgery information 9054. Additionally, any surgical complications 9056 are noted and  
9 also associated with the surgery which in turn has an associated note ID.

10 Referring now to Figure 4A, the logical data structure for notes and its description  
11 is continued. An assessment plan 9058 is created and associated with the same note ID for  
12 the particular patient. The plan has a free text field that allows a physician to create the  
13 appropriate assessment plan and associate it with a note ID 9042.

14 Various daily notes are also kept and associated with the individual note ID 9042.  
15 For example, the daily mental state 9060 is recorded to document the mental state of the  
16 patient. The daily treatment 9062 administered to the patient is associated with the unique  
17 note ID. The daily diagnosis 9068 is also created and associated with unique note ID  
18 9042.

19 Any unstable conditions are also noted 9070 and records kept of those conditions.  
20 Similarly mortality performance measures (MPM) information 9072 is kept and associated  
21 with the unique note ID. To the extent that any physical exam 9074 is administered, that  
22 physical exam and any free text created by the physician is associated with the unique ID  
23 and records kept. Allergy information 9076 for the particular patient is also created and  
24 stored along with the allergy type, and allergy name. This information is uniquely  
25 associated with the note ID. Referring now to Figure 4B, the Logical Data Structure for  
26 the Notes Creation and Storage description is continued. A specific note item record 9078  
27 is also kept and associated with unique note ID. This note item comprises the principal  
28 diagnosis, the chief complaint, the past history of the patient, the reason for the note, and  
29 various other identifications and flags of information which help in documenting the  
30 patient's condition.

31 Any drugs that are administered to the patient, including dosage, type, and number  
32 9086 is kept and associated with the unique note ID 9042.

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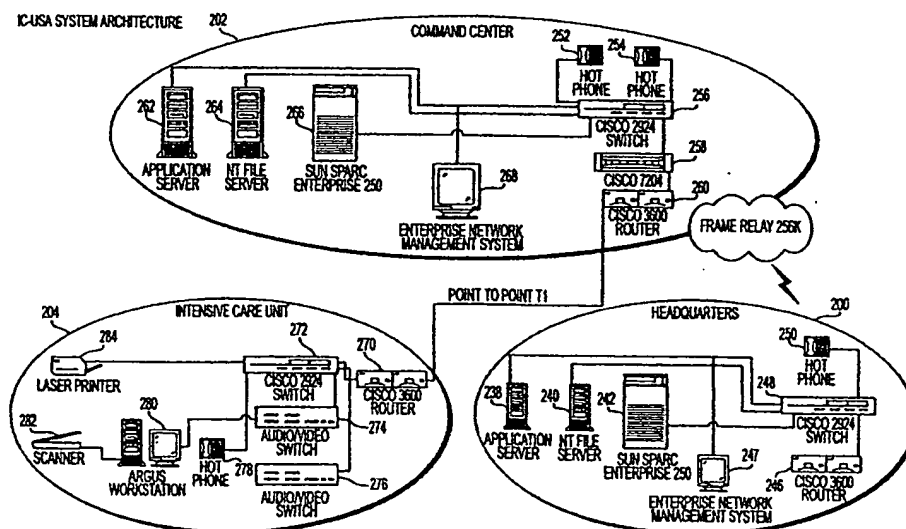
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(57) Abstract: A system and method for providing continuous expert network critical care services from a remote location. A plurality of intensive care units (ICU's) with associated patient monitoring instrumentation is connected over a network to a command center which is manned by intensivists 24 hours a day, 7 days a week. The intensivists are prompted to provide critical care by a standardized series of guideline algorithms for treating a variety of critical care conditions. Intensivists monitor the progress of individual patients at remote intensive care units. A smart alarm system provides alarms to the intensivists to alert the intensivists



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**A. CLASSIFICATION OF SUBJECT MATTER**  
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**B. FIELDS SEARCHED**

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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	H LEE ET AL: "REMOTE PATIENT MONITORING SERVICE THROUGH WORLD-WIDE WEB" ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY,US,NEW YORK, NY: IEEE, 30 October 1997 (1997-10-30), pages 928-931, XP002129894 ISBN: 0-7803-4263-1 the whole document	1-15
X	US 5 822 544 A (VINCENS JOE ET AL) 13 October 1998 (1998-10-13) abstract column 3, line 16 -column 4, line 29	1-11

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 574 828 A (HAYWARD ROBERT S A ET AL) 12 November 1996 (1996-11-12) column 2, line 26 -column 3, line 2 abstract -----	3,7,8, 13-15
A	XIN LI ET AL: "A World Wide Web telemedicine system" PROCEEDINGS OF THE SPIE,US,SPIE, BELLINGHAM, VA, vol. 2711, 13 February 1996 (1996-02-13), pages 427-439, XP002083082 the whole document figure 1 -----	3,7,13, 15

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5822544 A	13-10-1998	US 5465082 A	07-11-1995
		US 5291399 A	01-03-1994
		AT 179535 T	15-05-1999
		AU 691491 B	21-05-1998
		AU 6394494 A	11-10-1994
		CA 2157405 A	29-09-1994
		DE 69418188 D	02-06-1999
		DE 69418188 T	23-12-1999
		EP 0689699 A	03-01-1996
		ES 2132398 T	16-08-1999
		WO 9422098 A	29-09-1994
		US 5594786 A	14-01-1997
		US 5689229 A	18-11-1997
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